CLAIMS

1. A controlled release oral dosage form comprising 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof, dispersed in a carrier comprising a pharmaceutically acceptable waxy mixture of glyceride-based materials, having an HLB value of 4 to 12, and an average melting point in the range of 50 to 55°C.

2. A controlled release oral dosage form comprising 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof, dispersed in a carrier comprising a mixture of
(a) a pharmaceutically acceptable waxy mixture of glyceride-based materials having an HLB value of greater than 12 and an average melting point in the range of 50 to 55°C, and an amount of
(b) a pharmaceutically acceptable fatty acid glyceride or glyceride mixture having an HLB value less than the HLB value of component (a) and an average melting point in the range of 50 to 55°C,
such that the carrier as a whole has an HLB value of 4 to 12.

3. A controlled release oral dosage comprising a first composition and a second composition, each composition comprising 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof and a pharmaceutically acceptable carrier therefor, wherein:
(a) the carrier of the first composition comprises a pharmaceutically acceptable waxy mixture of glyceride-based materials having a range of HLB values of 4 to 12 and an average melting point in the range of 50 to 55°C; and
(b) the carrier of the second composition comprises one or more pharmaceutically acceptable glyceride-based materials having a higher HLB value and/or lower average melting point than the carrier of the first composition.

4. An oral dosage form according to claim 3, in which the first and second compositions are arranged to release 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof ('the drug'), at differing release rates on administration such that the rate of release of the drug from the dosage form is substantially independent of pH.

5. An oral dosage form according to claim 4, in which the release rate of the drug from the second composition is substantially greater than from the first composition.

6. An oral dosage form according to claim 5, in which the second composition is an immediate release composition.

7. An oral dosage form according to claim 5, in which the first composition is a controlled release composition.

8. An oral dosage form according to any preceding claim, in which the pharmaceutically acceptable waxy mixture of glyceride-based materials is waxy material obtainable by an alcoholysis/esterification reaction between a vegetable oil and a polyethylene glycol.

9. An oral dosage form according to claim 8, in which the vegetable oil is a hydrogenated oil.

10. An oral dosage form according to claim 9, in which the vegetable oil is hydrogenated palm oil.

11. An oral dosage form according to claim 2, in which the fatty acids of the glyceride are predominantly palmitic and stearic acids.

12. An oral dosage form according to any preceding claim, in which the carrier and 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof are moulded to form a tablet.

13. An oral dosage form according to any one of claims 1 to 11, in which the carrier and 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof are filled into capsule shells to form swallow capsules.

14. A method for the treatment and/or prophylaxis of the Disorders of the Invention, which comprises administering an effective amount of a controlled release oral dosage form as claimed in any one of claims 1 to 13 to a sufferer in need thereof.

15. Use of 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof, and a pharmaceutically acceptable waxy mixture of glyceride-based materials in the manufacture of a controlled

oral dosage form according to any one of claims 1 to 13 for the treatment and/or prophylaxis of diabetes mellitus, conditions associated with diabetes mellitus and certain complications thereof.

16. A method of preparing a controlled release oral dosage form according to claim 1 which comprises dispersing 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof, in a molten carrier comprising a pharmaceutically acceptable waxy mixture of glyceride-based materials, having an HLB value of 4 to 12, and an average melting point in the range of 50 to 55°C, filling the molten mixture into tablet moulds or capsule shells, allowing the carrier to solidify, and optionally thereafter and maintaining the solidified dosage form at a temperature of at least 40°C, but below the melting point of the carrier, for a time sufficient to allow the carrier to achieve a stable polymorphic form.

17. A method of preparing a controlled release oral dosage form according to claim 2 which comprises dispersing 5-[4-[2-(N-methyl-N-(2 pyridyl)amino)ethoxy]benzyl]thiazolidine-2,4-dione or a pharmaceutically acceptable salt or solvate thereof, in a molten carrier comprising a mixture of
(a) a pharmaceutically acceptable waxy mixture of glyceride-based materials having an HLB value of greater than 12 and an average melting point in the range of 50 to 55°C, and an amount of
(b) a pharmaceutically acceptable fatty acid glyceride or glyceride mixture having an HLB value less than the HLB value of component (a) and an average melting point in the range of 50 to 55°C,
such that the carrier as a whole has an HLB value of 4 to 12,
filling the molten mixture into tablet moulds or capsule shells, allowing the carrier to solidify, and maintaining the solidified dosage form at a temperature of at least 40°C, but below the melting point of the carrier, for a time sufficient to allow the carrier to achieve a stable polymorphic form.